

vTv Therapeutics Announces 2020 Second Quarter Financial Results and Update

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HIGH POINT, N.C., Aug. 03, 2020 (GLOBE NEWSWIRE) -- <u>vTv Therapeutics Inc.</u> (Nasdaq:VTVT) today reported financial results for the second quarter ended June 30, 2020, and provided an update on the progress of its clinical programs.

"Building on the successful phase 2 study completed earlier this year with TTP399, we have been highly focused on advancing this promising candidate as an adjunct to insulin for type 1 diabetes into the next stage of clinical development," said Steve Holcombe, president and CEO. "To this end, we have been engaging with the FDA to determine the development path for TTP399 and are in the planning stages for our first pivotal study, which we anticipate commencing by the end of 2020. We have also continued to enroll patients in our phase 2 study of azeliragon for the treatment of Alzheimer's disease in patients with type 2 diabetes, despite the clinical challenges posed by COVID-19."

Recent Achievements and Outlook

Type 1 Diabetes

- FDA Engagement and Pivotal Study Planning. Following a Type C Meeting request, vTv received written feedback from the FDA in June regarding the design of the Company's proposed pivotal studies. vTv expects to commence the next study for TTP399 by the end of 2020 with a six-month treatment period and a six-month open label extension. A second study with a 6-month treatment period would be initiated within 12 months after initiation of the first trial.
- Two Presentations at ADA of Simplici-T1 Study Results. Dr. John Buse, University of North Carolina at Chapel Hill, and Dr. Carmen Valcarce, chief scientific officer, made separate presentations at the American Diabetes Association's 80 th Scientific Sessions on the results of the Simplici-T1 Study in which TTP399 improved HbA1c in patients with type 1 diabetes, while reducing insulin dose and lowering the incidence of hypoglycemia and diabetic ketoacidosis.

Dementia with Diabetes

- Enrollment continues for Phase 2 Elevage Study of azeliragon. vTv continues to enroll patients in the Elevage Study to evaluate the efficacy and safety of azeliragon in patients with probable mild Alzheimer's disease (AD) and type 2 diabetes. Recruitment for the study will conclude by September 30, 2020 with a target of approximately 50 patients enrolled. The Company expects to report topline results from this study in the second quarter of 2021.
- Additional Clinical Data from STEADFAST Presented at AAIC. Dr. Aaron Burstein, SVP clinical development, presented additional clinical data at the Alzheimer's Association International Conference of the impact of azeliragon on the individual components of CDR-sb and ADAS-cog, the two primary instruments used to evaluate Alzheimer's disease.

Financing Activities

During the second quarter, vTv entered into agreements in order to provide additional financial flexibility and availability of additional capital to fund its near-term operations.

- Amendment to the Loan Agreement. On July 29, 2020, vTv entered into the Third Amendment to the Company's existing Loan Agreement to allow monthly, interest-only payments on the outstanding principal balance for two additional months beginning July 1, 2020 and to extend the maturity date of the first tranche from August 1 to September 1, 2020. The Third Amendment also eliminates the requirement for the Company to maintain a minimum cash balance.
- **ATM Sales**. Under the Controlled Equity OfferingSM Sales Agreement with Cantor Fitzgerald, vTv sold shares of its Class A common stock having an aggregate offering price of \$7.6 million as of the end of the second quarter.

Second Quarter 2020 Financial Results

- Cash Position: The Company's cash position as of June 30, 2020, was \$6.4 million compared to \$0.4 million as of March 31, 2020.
- Revenue: Revenues were insignificant for both the first and second quarter of 2020.
- **R&D Expenses**: Research and development expenses were \$2.5 million and \$4.2 million for the three months ended June 30, 2020 and March 31, 2020, respectively. This decrease of \$1.7 million was driven primarily by a decrease of \$0.5 million related to the development of TTP399, as the Simplici-T1 Study was completed in early 2020. Further, costs related to the development of azeliragon decreased approximately \$0.8 million related to lower costs incurred for the Elevage Study due to a slowdown in enrollment caused, in part, by COVID-19.
- G&A Expenses: General and administrative expenses were \$1.7 million for the second quarter of 2020 and \$2.5 million for the first quarter, respectively. The decrease of \$0.8 million was driven by lower professional fees, an adjustment made to the Company's asset retirement obligation recorded in connection with a leased facility, and overall expense curtailment.
- Net Loss Before Non-Controlling Interest: Net loss before non-controlling interest was \$5.0 million for the second quarter of 2020 compared to \$7.2 million for the first quarter of 2020.
- Net Loss Per Share: GAAP net loss per share was \$0.07 and \$0.11 for the three months ended June 30, 2020 and March 31, 2020, respectively, based on weighted-average shares of 45.7 million and 43.5 million for the three-month periods ended June 30, 2020 and March 31, 2020, respectively. Non-GAAP net loss per fully exchanged share was \$0.08 and \$0.11 for the three months ended June 30, 2020 and March 31, 2020 and March 31, 2020, respectively, based on non-GAAP fully exchanged weighted-average shares of 68.8 million and 66.6 million for the three months ended June 30, 2020 and March 31, 2020, respectively.

vTv Therapeutics Inc. Condensed Consolidated Balance Sheets (in thousands)

	June 30, 2020 (Unaudited)	March 31 2020 (Unaudited)
Assets		
Current assets:		
Cash and cash equivalents	\$ 6,392	\$ 406
Restricted cash and cash equivalents	_	2,500
Accounts receivable, net	_	5
Prepaid expenses and other current assets	299	591
Current deposits	87	_
Total current assets	6,778	3,502
Property and equipment, net	412	434
Operating lease right-of-use assets	514	529
Long-term investments	2,480	2,480
Long-term deposits	444	444
Total assets	\$ 10,628	\$ 7,389
Liabilities, Redeemable Noncontrolling Interest and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses	\$ 6,697	\$ 7,395
Operating lease liabilities	143	136
Current portion of contract liabilities	31	31
Current portion of notes payable	4,543	4,408
Total current liabilities	11,414	11,970
Contract liabilities, net of current portion	1,025	1,025
Operating lease liabilities, net of current portion	756	795
Warrant liability, related party	3,529	2,964
Other liabilities	54	260
Total liabilities	16,778	17,014
Commitments and contingencies		
Redeemable noncontrolling interest	63,378	52,196
Stockholders' deficit:		
Class A Common Stock	479	447

Class B Common Stock	232	232	
Additional paid-in capital	198,634	190,200	
Accumulated deficit	(268,873) (252,700)
Total stockholders' deficit attributable to vTv Therapeutics Inc.	(69,528) (61,821)
Total liabilities, redeemable noncontrolling interest and stockholders' deficit	\$ 10,628	\$ 7,389	

vTv Therapeutics Inc. Condensed Consolidated Statements of Operations - Unaudited (in thousands, except per share data)

	Three Months En June 30, 2020	ded	March 31, 2020	
Revenue	\$ —		\$8	
Operating expenses:				
Research and development	2,509		4,204	
General and administrative	1,695		2,450	
Total operating expenses	4,204		6,654	
Operating loss	(4,204)	(6,646)
Interest income	_		12	
Interest expense	(222)	(168)
Other (expense) income, net	(565)	(363)
Loss before income taxes and noncontrolling interest	(4,991)	(7,165)
Income tax provision	—		—	
Net loss before noncontrolling interest	(4,991)	(7,165)
Less: net loss attributable to noncontrolling interest	(1,623)	(2,441)
Net loss attributable to vTv Therapeutics Inc.	\$ (3,368)	\$ (4,724)
Net loss attributable to vTv Therapeutics Inc. common shareholders	\$ (3,368)	\$ (4,724)
Net loss per share of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	\$ (0.07)	\$ (0.11)
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	45,661,221		43,462,551	

vTv Therapeutics Inc. Condensed Consolidated Statements of Operations (in thousands, except per share data)

	Three Months Ended June 30,				For the Six N June 30,	Months Ended		
	2020		2019		2020		2019	
	(Unaudited)				(Unaudited)			
Revenue	\$ —		\$1,828		\$8		\$2,749	
Operating expenses:								
Research and development	2,509		4,228		6,713		7,050	
General and administrative	1,695		2,392		4,145		4,778	
Total operating expenses	4,204		6,620		10,858		11,828	
Operating loss	(4,204)	(4,792)	(10,850)	(9,079)
Interest income	—		16		12		26	
Interest expense	(222)	(514)	(390)	(1,140)
Other (expense) income, net	(565)	276		(928)	1,197	
Loss before income taxes and noncontrolling interest	(4,991)	(5,014)	(12,156)	(8,996)
Income tax provision	—		100		—		100	
Net loss before noncontrolling interest	(4,991)	(5,114)	(12,156)	(9,096)
Less: net loss attributable to noncontrolling interest	(1,623)	(2,232)	(4,064)	(4,059)
Net loss attributable to vTv Therapeutics Inc.	\$ (3,368)	\$ (2,882)	\$ (8,092)	\$ (5,037)
Net loss attributable to vTv Therapeutics Inc. common shareholders	\$ (3,368)	\$ (2,882)	\$ (8,092)	\$ (8,765)
Net loss per share of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	\$ (0.07)	\$ (0.10)	\$ (0.18)	\$ (0.34)
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	45,661,221		28,037,628		44,561,886		25,464,562	

About vTv Therapeutics

vTv Therapeutics Inc. is a clinical-stage biopharmaceutical company focused on developing oral small molecule drug candidates. vTv has a pipeline of clinical drug candidates led by programs for the treatment of type 1 diabetes, Alzheimer's disease, and inflammatory disorders. vTv's development partners are pursuing additional indications in type 2 diabetes, chronic obstructive pulmonary disease (COPD), and genetic mitochondrial diseases.

Forward-Looking Statements

This release contains forward-looking statements, which involve risks and uncertainties. These forward-looking statements can be identified by the use of forward-looking terminology, including the terms "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and, in each case, their negative or other various or comparable terminology. All statements other than statements of historical facts contained in this release, including statements regarding the timing of our clinical trials, our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Important factors that could cause our results to vary from expectations include those described under the heading "Risk Factors" in our Annual Report on Form 10-K and our other filings with the SEC. These forward-looking statements reflect our views with respect to future events as of the date of this release and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These forward-looking statements, whether as a result of new information, future events or otherwise after the date of this release. We anticipate that subsequent events and developments will cause our views to change. Our forward-looking statements do not reflect the potential impact of any future acquisitions, merger, dispositions, joint ventures or investments we may undertake. We qualify all of our forward-looking statements by these cautionary statements.

Non-GAAP Financial Measures

To supplement our consolidated financial statements, which are prepared and presented in accordance with generally accepted accounting principles in the U.S. ("GAAP"), we use non-GAAP adjusted net loss per fully exchanged share, which is a non-GAAP financial measure. Non-GAAP adjusted net loss per fully exchanged share adjusts the net loss attributable to vTv common shareholders for the impact of adjustments related to outstanding warrants, share-based compensation expense and the portion of net loss attributable to the noncontrolling interest. It also assumes the exchange of all the Class B common stock of vTv Therapeutics Inc. and an equal number of non-voting common units of vTv Therapeutics LLC ("vTv Units") for shares of Class A common stock of vTv Therapeutics Inc. We believe that this measure provides useful information to investors as it eliminates the variability of non-controlling interest resulting from the exchanges of Class B common stock and vTv Units into Class A common stock and other items of a non-cash nature. This measure is not intended to be considered in isolation or as a substitute for, or superior to, financial measures prepared and presented in accordance with GAAP.

The following is a reconciliation of non-GAAP adjusted net loss per fully exchanged share, basic and diluted to its most directly comparable GAAP measure, net loss per share of vTv Therapeutics Inc. Class A common stock, basic and diluted and the computation of the components of this non-GAAP measure:

		Ended	March 31,2020		
Numerator:					
Net loss attributable to vTv Therapeutics Inc. common shareholders	\$ (3,368)	\$ (4,724)	
Other income - related party	(565)	(363)	
Share-based compensation expense	186		380		
Deemed distribution to related party	—		—		
Reallocation of net income attributable to noncontrolling interest from the assumed exchange of Class B shares ⁽¹⁾	(1,623)	(2,441)	
Adjusted net loss before noncontrolling interest	\$ (5,370)	\$ (7,148)	
Denominator:					
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	45,661,221		43,462,551		
Assumed exchange of Class B Common Stock ⁽¹⁾	23,094,221		23,094,221		
Adjusted proforma fully exchanged weighted-average shares of Class A common stock outstanding, basic and diluted	68,755,442		66,556,772		
Adjusted net loss per fully exchanged share, basic and diluted	\$ (0.08)	\$ (0.11)	

Three Months Ended June 30,			Six Month	,			
2020		2019		2020		2019	
\$ (3,368)	\$ (2,882)	\$ (8,092)	\$ (8,765)
(565)	275		(928)	1,196	
186		401		566		682	
—		_		—		3,728	
	2020 \$ (3,368 (565	2020 \$ (3,368) (565)	2020 2019 \$ (3,368) \$ (2,882) (565) 275	2020 2019 \$ (3,368) \$ (2,882) (565) 275	2020 2019 2020 \$ (3,368) \$ (2,882) \$ (8,092 (565) 275 (928	2020 2019 2020 \$ (3,368) \$ (2,882) \$ (8,092) (565) 275 (928)	2020 2019 2020 2019 \$ (3,368) \$ (2,882) \$ (8,092) \$ (8,765) (565) 275 (928) 1,196 186 401 566 682

Reallocation of net income attributable to noncontrolling interest from the assumed exchange of Class B shares ⁽¹⁾	(1,623)	(2,232)	(4,064)	(4,059)
Adjusted net loss before noncontrolling interest	\$ (5,370)	\$ (4,438)	\$ (12,518)	\$ (7,218)
Denominator:								
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	45,661,221		28,037,628		44,561,886		25,464,562	
Assumed exchange of Class B Common Stock ⁽¹⁾	23,094,221		23,094,221		23,094,221		23,094,221	
Adjusted proforma fully exchanged weighted-average shares of Class A common stock outstanding, basic and diluted	68,755,442		51,131,849		67,656,107		48,558,783	
Adjusted net loss per fully exchanged share, basic and diluted	\$ (0.08)	\$ (0.09)	\$ (0.19)	\$ (0.15)

(1) Assumes the exchange of all outstanding Class B common stock, resulting in the elimination of the noncontrolling interest and recognition of the net income attributable to noncontrolling interests.

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Source: vTv Therapeutics Inc.